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**A phase I trial of intratumoral administration of CCL21-gene modified dendritic cell (DC) combined with intravenous pembrolizumab for advanced NSCLC**

**Grant Award Details**

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A phase I trial of intratumoral administration of CCL21-gene modified dendritic cell (DC) combined with intravenous pembrolizumab for advanced NSCLC

**Grant Type:** Clinical Trial Stage Projects

**Grant Number:** CLIN2-10784

**Project Objective:** Complete a phase I trial of intratumoral administration of CCL21-gene modified dendritic cell (DC) combined with intravenous pembrolizumab for advanced NSCLC

**Investigator:**

<b>Name:</b>	Steven Dubinett
<b>Institution:</b>	University of California, Los Angeles
<b>Type:</b>	PI

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**Disease Focus:** Cancer, Lung Cancer, Solid Tumors

**Human Stem Cell Use:** Adult Stem Cell

**Award Value:** \$11,815,315

**Status:** Pre-Active

**Grant Application Details**

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**Application Title:** A phase I trial of intratumoral administration of CCL21-gene modified dendritic cell (DC) combined with intravenous pembrolizumab for advanced NSCLC

**Public Abstract:****Therapeutic Candidate or Device**

Combination therapy with adenoviral CCL21 gene-modified DC and pembrolizumab

**Indication**

Patients with confirmed and measurable stage IV NSCLC expressing PD-L1 in less than 50% of cells who are naïve to systemic treatment for NSCLC.

**Therapeutic Mechanism**

The central rationale this approach is to utilize in situ vaccination with intratumoral injection of functional antigen presenting cells that take advantage of the full repertoire of available tumor antigens. We, and others, have found that this can convert the tumor site into a lymph node-like environment and thus promote specific T lymphocyte activation both locally and systemically.

**Unmet Medical Need**

~80% of NSCLC patients treated with anti-PD-1 do not respond. We have found that IT injection of Ad-CCL21-DC can induce tumoral CD8 T lymphocyte, enhance tumor antigen presentation in situ, and trigger systemic antitumor immunity. This supports the rationale for combination therapy.

**Project Objective**

Completion of phase 1 combination therapy

**Major Proposed Activities**

- GMP manufacture of gene modified autologous cellular product
- phase 1 dose escalation and expansion cohorts for combination therapy
- Monitoring of clinical and immune responses

**Statement of Benefit to California:**

Each year many Californians are diagnosed with lung cancer. The majority of patients are diagnosed with advanced disease. Because 5 year survival in advanced disease is less than 5%, lung cancer is the state's leading cause of cancer related death. This combination therapy could afford a major opportunity for a new and effective therapy for the 80% of patients who do not respond to immunotherapy. This form of therapy may also be broadly applicable to other types of malignancies.

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**Source URL:** <https://www.cirm.ca.gov/our-progress/awards/phase-i-trial-intratumoral-administration-ccl21-gene-modified-dendritic-cell-dc>